

PRESS RELEASE

Cincinnati, Ohio, USA, MedDRA® Management Board Meeting

**MedDRA Management Board Congratulates CIOMS Working Group on SMQs
for its Important Contribution to Public Health Protection**

Cincinnati, 12 June 2011 – The MedDRA Management Board met in Cincinnati, Ohio, USA on 11 - 12 June 2011.

The MedDRA Management Board welcomed news of the completion of the current phase of development work on Standardized MedDRA Queries (SMQs) by the CIOMS Working Group on this topic. The Board noted that by the time of the release of MedDRA 15.0 in March 2012 a total of 90 SMQs will be available to MedDRA users. The Board conveyed its congratulations to the Working Group for this significant achievement and recognized the benefit of these important signal detection tools for the protection of public health.

Members of the ICH Global Cooperation Group from beyond the ICH regions were invited to a special session of the Board. Regulatory and industry representatives on the Board provided their perspectives on the benefits of using MedDRA in clinical trials. Presentations were also given by representatives from the Singapore Health Sciences Authority (HSA) and the Chinese State Food and Drug Administration (SFDA). The Singapore representative reported on their experiences in implementing MedDRA and gave the Board positive feedback on recent ICH-sponsored training in their country.

The Board reviewed results of a survey of users of the MedDRA Web-based Browser. Over 300 MedDRA users responded to the survey. The Board noted the high-level of satisfaction with the browser and that additional specific input from responders will be used to continue to improve the tool.

The Board was pleased to hear the progress made to date on the development of the MedDRA Version Analysis Tool. The MSSO expects the tool to be available late 2011.

The Japanese Management Board (JMB) reported on the activities of the Japanese Maintenance Organization (JMO). They noted that a substantial number of subscribers in Japan participate in the “explanatory meetings” that the JMO holds after each release of MedDRA, reflecting a continued high interest among subscribers in changes to MedDRA.

The next scheduled meeting of the Board will be on 5 – 6 November 2011 in Seville, Spain.

For further information, please contact:

ICH Secretariat, c/o IFPMA, Chemin Louis-Dunant, 15, P.O Box 195, 1211 Geneva 20,
Switzerland Tel: +41 22 338 3206
Fax: +41 22 338 3230
E-mail: admin@ich.org - Web site: www.ich.org